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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,114	12/01/2003	Michael Berthon-Jones	3869-019	7777
22440	7590	09/08/2004	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC			MITCHELL, TEENA KAY	
270 MADISON AVENUE			ART UNIT	PAPER NUMBER
8TH FLOOR			3743	
NEW YORK, NY 100160601			DATE MAILED: 09/08/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,114	BERTHON-JONES, MICHAEL	
	Examiner Teena Mitchell	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 19-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 08/911,513.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/01/03; 7/19/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/911,513, filed on 08/14/1997.

While applicant has made reference in the first paragraph of the disclosure that the instant application is a Continuation of application 09/902,011, applicant is also required to note the current status of application 09/902,011, which is US Patent 6,659,101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Froehlich et.al. (5,551,419).

With respect to claim 19, Froehlich in CPAP device discloses:

- a mask (11);

- a conduit (14) with a proximate end and a distal portion, wherein the proximate end is coupled to the mask ((Fig. 1);
- a controllable pressure delivery device (10) coupled to the distal portion of the conduit (14), the device (10) for providing a gas at a pressure above atmospheric to the airway of the patient through the mask (11) and conduit (14);
- a pressure sensor (16) configured to provide a distal pressure signal proportional to the pressure at the pressure delivery device (12);
- wherein the pressure delivery device comprises a processor (17) configured and adapted to select a desired mask pressure for setting a delivery pressure for the patient (via 23);
- continuously determine a pressure characteristic for the conduit (via 15, 16, detects inspiration/expiration); calculate an estimated mask pressure as a function of the distal pressure signal (such as pressure drop) and the determined pressure characteristic (Abstract; Col. 2, lines 35-51 and Col. 6, lines 48-67 and Col. 7, lines 1-15);
- control of the pressure delivery device to deliver the desired mask pressure as a function of the estimated mask pressure (Abstract; Col. 2, lines 35-51; Col. 6, lines 48-67 and Col. 7, lines 1-15).

With respect to claim 20, Froehlich discloses a flow sensor (15) configured to provide a flow signal representative of airflow in the conduit (Col. 4, lines 32-63) and wherein the processor (17) is configured and adapted to determine the pressure

characteristic for the conduit as a function of the flow signal (Abstract; Col. 6, lines 48-67 and Col. 7, lines 1-15).

With respect to claim 21, Froehlich discloses wherein the processor (17) is configured and adapted to calculate the estimate mask pressure by subtracting the pressure characteristic from a measure of the distal pressure signal (Col. 7, lines 1-15).

With respect to claim 22, Froehlich does not explicitly state that empirically determined constants are used, however it would be inherent that such is used inasmuch as an algorithm is used and based on stored data (Col. 6, lines 28-67 and Col. 7, lines 1-62).

With respect to claim 23, Froehlich discloses wherein the processor (17) is configured and adapted to determine the pressure characteristics by calculating the pressure characteristic as a function of a sign of the measure of airflow and a sign of a squared measured of airflow (Col. 6, lines 28-67 and Col. 7, lines 1-50; Col. 8, lines 19-36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehlich et.al. (5,551,419).

With respect to claims 24-28, Froehlich discloses a controllable pressure delivery device (10) with a mask (11) and conduit (14), a pressure sensor (16) and a flow sensor (15). The claimed method steps would have been obvious because they would have resulted from the use of the device recited in claims 19-23 above.

With respect to claim 29, Froehlich discloses continuously determining a pressure drop to the mask (Col. 2, lines 35-66; Col. 6, lines 28-67 and Col. 7, lines 1-15). The claimed method steps would have been obvious because they would have resulted from the use of the device of Froehlich.

With respect to claim 30, Froehlich discloses the pressure drop is a function of the measured airflow (Col. 6, lines 48-67 and Col. 7, lines 1-15). The claimed method step would have been obvious because it would have resulted from the use of the device of Froehlich.

With respect to claim 31, Froehlich discloses subtracting the pressure drop (Col. 6, lines 48-67 and Col. 7, lines 1-15).

With respect to claim 32, note rejection of claim 27 above.

With respect to claim 33, Froehlich discloses wherein the pressure drop of the conduit (14) is calculated as a function of he measure of airflow and a sign of a squared measure of airflow (Col. 6, lines 28-67 and Col. 7, lines 1-50; Col. 8, lines 19-36).

With respect to claim 34, Froehlich discloses controlling the airway pressure treatment is a function of the calculated pressure at the mask (via 16, 15, 17; Col. 2, lines 35-51; Col. 6, lines 28-65).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show ventilator devices for determining respiratory airflow: 6,659,101; 6,427,689; 6,279,569; 6,152,129; 5,794,614.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Examiner
Art Unit 3743
September 3, 2004